

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS
REGISTRATION DIVISION (7505P)

April 19, 2021

MEMORANDUM:

Subject: Acute Toxicity Review for EPA Reg. No / File Symbol: 70506-ANO

Applicant: UPL NA, Inc.
Product Name: Shenzi WG Insecticide
DP Barcode: D463891
Decision No.: 578426
Action Code: R310
PC Code(s): 090100 (Chlorantraniliprole; 70%)

From: Bonaventure A. Akinlosotu, PhD [*eSigned - B.A. Akinlosotu*]
Chemistry, Inerts and Toxicology Assessment Branch (CITAB)/Toxicology Team

To: Jasmin Jackson/Venus Eagle, RM Team 01
IVB3
Registration Division (7505P)

FORMULATION FROM LABEL:

<u>Active Ingredient(s):</u>	<u>% by wt.</u>
Chlorantraniliprole	70.00
<u>Other Ingredients:</u>	<u>30.00</u>
Total:	100.00

BACKGROUND:

The registrant (UPL NA, Inc.) applied to register the subject proposed insecticide product containing the active ingredient, Chlorantraniliprole.

The Agency reviewed the data submitted for the six studies (MRID Nos 51664809 thru 51664814) to assess the acute toxicity, irritation, and sensitization potential of the proposed product (see Toxicity Profile – below under Findings). It was determined that these data are acceptable to support the registration of the proposed product.

The Product Chemistry data (including the basic and any alternate formulations/CSFs) must be reviewed and found acceptable by the Agency. The proposed label was screened as it pertains to the acute toxicity requirements. The final review of the labeling (uses, use directions, storage/disposal, etc.) is the purview of the RM team.

GLP: All studies were conducted in accordance with GLP.

Deficiencies: None

Findings (Comments and Recommendations):

The following six studies are classified as acceptable and satisfy the acute toxicity data requirements for the registration of the proposed product (EPA File Symbol 70506-ANO). The following constitutes the toxicology profile:

acute oral toxicity	IV	acceptable	MRID 51664809
acute dermal toxicity	III	acceptable	MRID 51664810
acute inhalation toxicity	IV	acceptable	MRID 51664811
primary eye irritation	IV	acceptable	MRID 51664812
primary dermal irritation	IV	acceptable	MRID 51664813
dermal sensitization	-ve	acceptable	MRID 51664814

Precautionary Labeling*:

Product Reg. No.: 070506-00609

Product Name: Shenzi WG Insecticide

PRECAUTIONARY STATEMENTS

KEEP OUT OF THE REACH OF CHILDREN

SIGNAL WORD: CAUTION

Hazards to Humans and Domestic Animals:

Harmful if absorbed through the skin. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse. Wear long-sleeved shirt and long pants, shoes plus socks and appropriate waterproof and/or chemical-resistant gloves.

First Aid

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

User Safety Recommendations:

Applicators and other handlers should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change clothing.

***Notes to PM/RM Reviewer:**

Revise the precautionary statements to include "Wear long-sleeved shirt and long pants, shoes plus socks and appropriate waterproof and/or chemical-resistant gloves.". Subsequently, you may accept/approve the precautionary labeling on the proposed label.

DATA EVALUATION RECORD

Reviewers: Bonaventure Akinlosotu, Ph.D.
Donna L. Fefee, DVM (Summitec Corp.)

Date: April 18, 2022

Product Reg. No./File Symbol: 70506-ANO

1. DP BARCODE: 463891				
2. PC CODE: 090100				
3. CURRENT DATE: April 18, 2022				
4. TEST MATERIAL: GPI 420: Chlorantraniliprole 700 g/Kg WG (equivalent to Chlorantraniliprole 70% w/w WG): 71.10% Chlorantraniliprole; Batch/Lot no. ARD/GPI420/07092020-1; CAS no. 500008-45-7; JRF test item code: GPI445; Off-white colored granules, free from visible extraneous matter and hard lumps; pH: 5.65 (1% solution in distilled water at room temperature), per JRF; expiration date: September 6, 2022; stored at room temperature (15-30°C), in its original container, protected from direct sunlight				
Study/Strain & Species/Lab Study # /Date	MRID	Results	Tox Cat	Core Grade
Acute oral toxicity/ Wistar albino rat (UDP) JAI Research Foundation (Valsad, Gujarat, India) Study no. 401-1-01-27216 June 15, 2021 OCSPP 870.1100; OECD 425	51664809	LD₅₀ > 5000 mg/kg bw 3 fasted female rats were treated with the test material in reverse osmosis water (500 mg/mL) at a dose level of 5000 mg/kg bw (10 mL/kg bw dosing volume). There were no mortalities, abnormal clinical signs, or abnormal gross necropsy findings. All the animals gained weight during both weeks of the study.	IV	A
Acute dermal toxicity/ Wistar albino rat JAI Research Foundation (Valsad, Gujarat, India) Study no. 403-1-01-27217 June 11, 2021 OCSPP 870.1200; OECD 402	51664810	LD₅₀ > 2000 mg/kg bw 3 female rats were dermally exposed for 24 hrs to 2000 mg/kg bw of ground test material moistened with 0.5 mL of reverse-osmosis water. There were no mortalities, abnormal gross necropsy findings, or abnormal clinical signs. No erythema or edema was seen at 24, 48, or 72 hours after patch removal. All animals gained weight during both weeks of the study.	III	A
Acute inhalation toxicity/ Wistar albino rats (4hr, Nose-only) JAI Research Foundation (Valsad, Gujarat, India) Study no. 405-1-01-27218 May 18, 2021 OCSPP 870.1300; OECD 403	51664811	LC₅₀ (both sexes) > 5.263 mg/L 10 rats (5/sex) were exposed to aerosolized undiluted ground test material at 5.263 mg/L. Mean gravimetric conc.: 5.263 mg/L MMAD: 3.47 µm; GSD: 1.58 Nominal conc.: 12.086 mg/L.	IV	A

		There were no mortalities or abnormal gross necropsy findings. All the animals lost weight during Days 0-1, then gained weight during all subsequent weighing intervals, and had net weight gains for the study duration. No abnormal clinical signs were seen during exposure, upon removal from the chamber, or during the remainder of the study.		
<p>Primary eye irritation/ New Zealand albino rabbit</p> <p>JAI Research Foundation (Valsad, Gujarat, India) Study no. 407-1-01-27220 June 11, 2021</p> <p>OCSPP 870.2400; OECD 405</p>	51664812	<p>Minimally Irritating [No reported discharge scores; thus, MMTS and the descriptive (Kay and Calandra) rating couldn't be determined].</p> <p>The undiluted ground test material (0.1 mL; 80.28-81.04 mg) was instilled into the anesthetized right eye of 3 adult female rabbits. Both eyes of each rabbit were anesthetized with proparacaine HCl, and appropriate systemic analgesia was provided.</p> <p>Abnormal findings were limited to conjunctival redness and chemosis (scores=1) in 3/3 treated eyes one hour after dosing. Iritis and corneal opacity were not seen in the study; discharge was not scored or otherwise reported. Fluorescein staining at 24 hours did not reveal damage to the corneal epithelium. The animals gained weight and remained free of abnormal systemic clinical signs during the study.</p>	IV	A
<p>Primary dermal irritation/ New Zealand albino rabbit</p> <p>JAI Research Foundation (Valsad, Gujarat, India) Study no. 406-1-01-27219 June 10, 2021</p> <p>OCSPP 870.2500; OECD 404</p>	51664813	<p>Slight irritant Mean irritation at 72 hrs = 0.0 PDII = 1.0</p> <p>3 adult female rabbits were dermally exposed for 4 hours to 500 mg of ground test material moistened with 0.5 mL of distilled water.</p> <p>One hour after patch removal, 3/3 treated sites exhibited very slight, barely perceptible erythema and very slight, barely perceptible edema (all scores=1), and these signs persisted through 24 hours.</p>	IV	A

		At 48 and 72 hours, all treated sites were free of erythema and edema. No abnormal systemic clinical signs were noted, and the animals gained weight during the study.		
<p>Dermal sensitization/ CBA/J mouse (LLNA, individual animal approach)</p> <p>JAI Research Foundation (Valsad, Gujarat, India) Study no. 409-1-01-27221 June 12, 2021</p> <p>OCSPP 870.2600; OECD 429</p>	51664814	<p>Product is not a dermal sensitizer</p> <p>Based on preliminary testing, 25 female mice (5/group) were treated as follows: vehicle control (1% aqueous solution of Pluronic® L92); positive control (25% hexyl cinnamic aldehyde in the vehicle); and 10%, 25%, and 50% concentrations of the test material in the vehicle.</p> <p>The groups treated with the 10%, 25%, and 50% concentrations of the test material had stimulation indices (SIs) of 1.41, 1.17, and 1.50, respectively, while the SI for the positive control group was 6.08. (An SI value >3 is considered a positive response.)</p> <p><u>Note:</u> It was unclear whether a higher concentration than 50% was evaluated for homogeneity/solubility/usability.</p>	-ve	A

Core Grade Key: A =Acceptable, S = Supplementary, U = Unacceptable, D = Data Gap